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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/508,849      | 03/17/2000  | SHIGEKAZU NAGATA     | 1110-266PCT         | 5291             |

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EXAMINER

HARRIS, ALANA M

ART UNIT PAPER NUMBER

1642

DATE MAILED: 03/07/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/508,849

Applicant(s)

NAGATA ET AL.

Examiner

Alana M. Harris, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 13 December 2002.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 2-6 and 8-12 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 4 is/are allowed.
- 6) ☒ Claim(s) 2,3,6 and 8-12 is/are rejected.
- 7) ☐ Claim(s) 5 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                             | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)         | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____                                    |

**DETAILED ACTION**

***Response to Arguments***

1. Claims 2-6 and 8-12 are pending.  
Claims 2, 3, 6, 10 and 11 have been amended.  
Claim 12 has been added.  
Claims 2-6 and 8-12 are examined on the merits.
2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

***Maintained Grounds of Rejection***

***Claim Rejections - 35 USC § 112***

3. The rejection of claims 2, 3, 6, 10, 11 and newly added claim 12 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention is maintained and made.

Applicants claim the full Fas ligand sequence was known prior to the present invention and supply Accession number AAC50124 database sheet with the Remarks submitted December 13, 2002. Applicants aver that the recitation "natural human Fas ligand" is well known to those skilled in the art. Moreover, Applicants contend that the Examiner "...has ignored the numerous...features recited in the claims and apparently

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misunderstands the nature of the invention.” Applicants note that working examples have been described in the specification and “...are not required to disclose every species encompassed by a genus”. Applicants’ arguments have been fully considered but they are not persuasive.

Applicants have not set forth in the claims the sequence from which the claimed polypeptides should arise. In the specification there is no disclosure setting for the structure or function attributed to the natural human Fas ligand from which the claimed mutant and variant polypeptides are based upon. The written description requirement prevents an applicant from claiming subject matter that is not adequately described in the specification as filed. Applicants have not assigned a sequence identifying number to this natural human Fas ligand, nor set forth that the said ligand is the only naturally occurring human Fas ligand. Claims that omit an element which Applicants describe as an essential or critical feature of the invention originally disclosed does not comply with the written description requirement, see 1242 Official Gazette pages 172 and 173, January 30, 2001. The claims are not described sufficiently, nor supported by the specification adequately to glean Applicants’ had possession of the varied species encompassed by the wide breadth of the claims. It is clear that Applicants are in possession of one species of the natural human Fas ligand presented on page 7 of the Remarks, as well as the defined deletion polypeptides (SEQ ID NO: 1, SEQ ID NO: 2, D4, D5 and D6) based upon the said one natural human Fas ligand. Applicants’ specification does not disclose sufficient description of a representative number of species by disclosure of relevant, identifying characteristics, i.e. functional

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characteristics coupled with a known or disclosed correlation between function and structure.

Applicant is not entitled, nor is the specification enabled for the use of all human Fas ligand derivatives or soluble Fas ligands. There is insufficient to support the generic claims as provided by the Interim Written Description Guidelines published in the June 15, 1998 Federal Register at Volume 63, Number 114, pages 32639-32645. Applicant is referred to the revised interim guidelines concerning compliance with the written description requirement of U.S.C. 112, first paragraph, published in the Official Gazette and also available at [www.uspto.gov](http://www.uspto.gov).

4. The rejection of claims 8 and 9 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is maintained.

a. The recitation "novel" in claims 8 and 9 are indefinite in that the term is superfluous and does not further clarify the claimed subject matter. Applicant may obviate the instant rejection by amending the claim to recite "isolated polypeptide" or "purified polypeptide."

***Allowable Subject Matter***

5. Claim 4 is allowed.

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6. Claim 5 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

***Conclusion***

7. Claims 2-6 and 8-12 are free of the art.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alana M. Harris, Ph.D. whose telephone number is (703) 306-5880. The examiner can normally be reached on 6:30 am to 4:00 pm, with alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, Ph.D. can be reached on (703) 308-3995. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4315 for regular communications and (703) 308-4315 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

**ALANA HARRIS**  
**PATENT EXAMINER**



Alana M. Harris, Ph.D.  
March 6, 2003